

**ASPIRIN LOW STRENGTH- aspirin tablet, delayed release**  
**CVS Pharmacy**

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**CVS 44-645**

***Active ingredient (in each tablet)***

Aspirin 81 mg (NSAID)\*

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever

***Uses***

for the temporary relief of minor aches and pains or as recommended by your doctor. **Because of its delayed action, this product will not provide fast relief of headaches or other symptoms needing immediate relief.**

***Warnings***

**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

**Allergy alert:** Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthma (wheezing)

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- take a blood thinning (anticoagulant) or steroid drug
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]

**Do not use**

- if you are allergic to aspirin or any other pain reliever/fever reducer
- if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you have asthma
- you are taking a diuretic

**Ask a doctor or pharmacist before use if you are**

taking a prescription drug for

- gout
- diabetes
- arthritis

**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
  - feel faint
- ringing in the ears or a loss of hearing occurs
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

***Directions***

- **do not take more than directed**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor
- children under 12 years: do not use unless directed by a doctor

***Other information***

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

## ***Inactive ingredients***

colloidal anhydrous silica, corn starch, FD&C red #40, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, shellac wax, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

## ***Questions or comments?***

**1-800-426-9391**

## **Principal Display Panel**

**VALUE SIZE 365 TABLETS**

**♥CVS  
Health®**

Compare to the active ingredient in St. Joseph®  
Low Dose Safety Coated 81 mg Aspirin†

## **Coated Tablets**

Low Strength

**Aspirin**  
Pain reliever (**NSAID**)

81  
mg

Talk to your doctor or  
other healthcare provider  
before using this product  
for your heart.

Actual Size  
Safety Coated

**365 ENTERIC COATED TABLETS**

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY  
SEAL UNDER CAP IS BROKEN OR MISSING**

†This product is not manufactured or distributed by Foundation Consumer Healthcare, LLC, owner of the registered trademark St. Joseph® Low Dose Safety Coated 81 mg Aspirin.

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**VALUE SIZE** 365 TABLETS

**CVS Health.** Compare to the active ingredient in St. Joseph® Low Dose Safety Coated 81 mg Aspirin†

**Coated Tablets**

**Low Strength Aspirin**  
Pain reliever (NSAID)

**81 mg**

Talk to your doctor or other healthcare provider before using this product for your heart.

Actual Size Safety Coated

**365 ENTERIC COATED TABLETS**

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

**Drug Facts**

**Active ingredient (in each tablet)** Purpose  
Aspirin 81 mg (NSAID)\* ..... Pain reliever  
\*nonsteroidal anti-inflammatory drug

**Uses** For the temporary relief of minor aches and pains or as recommended by your doctor. Because of its delayed action, this product will not provide last relief of headaches or other symptoms needing immediate relief.

**Warnings**  
**Reye's syndrome:** Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.  
**Allergy alert:** Aspirin may cause a severe allergic reaction, which may include: ■ hives ■ facial swelling ■ shock ■ asthma (wheezing)  
**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you ■ are age 60 or older ■ take a blood thinning (anticoagulant) or steroid drug ■ have had stomach ulcers or bleeding problems ■ have 3 or more alcoholic drinks every day while using this product ■ take more or for a longer time than directed ■ take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)

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PEEL HERE FOR MORE DRUG FACTS

STOP PEELING

**Drug Facts (continued)**

**Do not use** ■ if you are allergic to aspirin or any other pain reliever/fever reducer ■ if you have ever had an allergic reaction to this product or any of its ingredients

**Ask a doctor before use if**  
 ■ stomach bleeding warning applies to you  
 ■ you have a history of stomach problems, such as heartburn ■ you are taking a diuretic  
 ■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease ■ you have asthma

**Ask a doctor or pharmacist before use if you are taking a prescription drug for** ■ gout ■ diabetes ■ arthritis

**Stop use and ask a doctor if**  
 ■ an allergic reaction occurs. Seek medical help right away.  
 ■ you experience any of the following signs of stomach bleeding: ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ feel faint or ringing in the ears or a loss of hearing occurs  
 ■ pain gets worse or lasts more than 10 days  
 ■ fever gets worse or lasts more than 3 days  
 ■ redness or swelling is present ■ new symptoms occur  
 These could be signs of a serious condition.

**If pregnant or breast-feeding,** ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions** ■ do not take more than directed  
 ■ drink a full glass of water with each dose  
 ■ adults and children 12 years and over: take 4 to 8 tablets every 4 hours not to exceed 48 tablets in 24 hours unless directed by a doctor ■ children under 12 years: do not use unless directed by a doctor

**Other information** ■ store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F) ■ use by expiration date on package

**Inactive ingredients** colloidal anhydrous silica, corn starch, FD&C red #40, FD&C yellow #6, hypromellose, methacrylic acid, microcrystalline cellulose, polydextrose, polyethylene glycol, stearic wax, simethicone, sodium bicarbonate, sodium lauryl sulfate, talc, titanium dioxide, triacetin, triethyl citrate

**Questions or comments?** 1-800-426-9391

CVS 44-645

## ASPIRIN LOW STRENGTH

aspirin tablet, delayed release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-945
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	81 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>METHACRYLIC ACID</b> (UNII: 1CS02G8656)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ05DW1A)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BICARBONATE</b> (UNII: 8MDF5V39QO)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	
<b>TRIETHYL CITRATE</b> (UNII: 8Z96QXD6UM)	

## Product Characteristics

<b>Color</b>	pink	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	6mm
<b>Flavor</b>		<b>Imprint Code</b>	L
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-945-32	1 in 1 CARTON	07/25/2014	
1		120 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:59779-945-51	365 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/25/2014	
3	NDC:59779-945-07	1 in 1 CARTON	07/25/2014	07/08/2018
3		36 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:59779-945-17	1 in 1 CARTON	07/25/2014	03/04/2018
4		300 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/25/2014	

**Labeler** - CVS Pharmacy (062312574)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		038154464	pack(59779-945)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867837	manufacture(59779-945)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(59779-945)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		868734088	manufacture(59779-945)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	pack(59779-945)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(59779-945)